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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 09/843,051 | Applicant(s) GERBER ET AL. | |
| | Examiner George R. Evanisko | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-13 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/05 has been entered.

Election/Restrictions

Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The inventions are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process not involving stimulation, but used for sensing. In addition, the method does not require the conductor extending between the connectors.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, and 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Speicher et al (4603705). Speicher is capable of meeting the functional use recitations presented in the claims since he use an implantable, flexible coil electrode, it is a similar size and shape as the applicants invention, and since it meets the claimed limitations. In addition, Speicher meets the claimed limitation of “about 2 mm” since his coil diameter is “about 3 mm” (col 5). Also, Speicher shows the electrode connectors (20, 22, 50, or 52) connected to one another in connection zones or adhered to (dictionary definition of adhered of “to give support” or “to hold fast or stick by”) since the coil electrode and connector are maintained in connection with each other to provide the

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implantable lead. Finally, Speicher shows the ring shaped electrode as the other coiled electrode or conductive electrode connectors 20, 22, 50, or 52.

In the alternative, Speicher discloses the claimed invention except for the coil diameter being from about 0.5 mm to about 2.0 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead with coil electrode as taught by Speicher, with a coiled electrode having a diameter of about 0.5 mm to about 2.0 mm since it was known in the art that implantable leads with coil electrodes use a coil electrode of about 0.5 mm to about 2.0 mm to provide an implantable lead having a coil electrode that is small and unobtrusive. In addition, one skilled in the art would have expected both the applicants claimed invention and Speicher's invention to have the same properties even though the ranges do not overlap since both are used for providing an implantable lead with flexible coiled electrodes. (According to MPEP 2144.05, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties).

Claims 3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speicher et al.

Speicher discloses the claimed invention except for the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead with coil electrode as taught by Speicher, with the electrode and connector being butt-welded together since it was

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known in the art that implantable leads use a butt-weld to connect electrodes and connectors to provide a secure and easily produced connection to connect the two elements together.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the implantable lead as taught by Speicher with the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters, because Applicant has not disclosed that the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode connector and coil electrode being connected together and the inner diameters not being substantially the same as taught by Speicher, because Speicher provides a coil electrode and connector that is flexible and implantable.

Therefore, it would have been an obvious matter of design choice to modify Speicher to obtain the invention as specified in the claim(s).

Claims 1, 2, 4, 8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schear (6251107). Schear provides a flexible coil electrode that can be intravascularly positioned and is of a similar size and shape of the applicant's invention and therefore is capable of meeting the functional use recitations presented in the claims. Also, any of the other coil electrodes can be considered to be the claimed "ring shaped electrode" located proximal or distal to a coil electrode. But Schear does not disclose an electrode connector connected/adhered in an

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annular connection zone to the electrode and mechanically and electrically connected to the conductor with the connector and electrode axially aligned and having substantially common outer and inner diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead with flexible coil electrodes as taught by Schaer, with an electrode connector connected/adhered in an annular connection zone to the electrode and mechanically and electrically connected to the conductor with the connector and electrode axially aligned and having substantially common outer and inner diameters since it was known in the art that leads using flexible coil electrodes use an electrode connector connected/adhered in an annular connection zone to the electrode and mechanically and electrically connected to the conductor with the connector and electrode axially aligned and having substantially common outer and inner diameters to provide a more secure connection of the conductor to the electrode that lessens /separation breakage of the conductor from the electrode, and allows the electrode to be securely attached to the electrode connector over the diameter of the electrode.

Response to Arguments

Applicant's arguments filed 6/15/05 have been fully considered but they are not persuasive.

The argument that Speicher does not meet the functional use recitations in the claims is not persuasive since Speicher (or Schaer) provides a flexible electrode (column 5, line 46 and figures 2 and 3), a flexible lead that is intravascularly inserted/positioned in the patient (column 3, line 51), and that is approximately the same size, shape, and/or construction as the applicants invention. Therefore, Speicher (or Schaer) is capable of meeting the functional use recitations

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presented in the claims. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

The arguments that the intended use does impart structural features to the claims because the “New Perspectives...” reference shows a lead would have to be about 6 cm to 9 cm and that areas between the sacral foramina are about 2-3 cm is not persuasive since these limitations are not claimed and since the claim states “for electrical stimulation of one or more sacral nerves”. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The use of “one or more” means that the prior art used to reject the claims only needs to stimulate at least one nerve and not all the nerves to anticipate/meet the claimed limitations. In addition, this can be seen in the last paragraph of claim 1 where the claim states the coil electrode is used to stimulate “at least one sacral nerve”. The prior art of Speicher and Schaer both provide flexible implantable coil electrodes that can/will stimulate at least one nerve. In addition, Speicher and Schaer may stimulate multiple nerves since the lead can be moved from nerve to nerve to stimulate more than one nerve (as is common practice when testing for the correct nerve to stimulate). It is noted the claims do not state “stimulating nerves with different electrodes” or “at the same time”.

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In addition, if the applicant's arguments, regarding Speicher and Schaer not being capable of stimulating the nerves, were persuasive, then the claims would not be enabling and would be incomplete for omitting essential critical elements since the claims do not contain the limitations (multiple electrodes, 6-9 cm, maximum length of the area to stimulate, etc) which applicant regards as necessary to stimulate several nerves.

The prior art of Speicher, Kroll et al (5265623), Hoffman et al (5534022) and Laske (5728149), are several examples of many that teach the use of an electrode connector connected/adhered in an annular connection zone to the electrode and mechanically and electrically connected to the conductor with the connector and electrode axially aligned and having substantially common outer and inner diameters.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

8/155

GRE
August 7, 2005